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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request; PHS Applications and Pre-award Related Reporting (Office of the Director)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or Email your request, including your address to ProjectClearanceBranch@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on April 12, 2021, pages 18992-18993 (86

FR 18992) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director (OD), Office of Policy and Extramural Research Administration (OPERA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Public Health Service (PHS) Applications and Pre-Award Reporting Requirements, Revision, OMB 0925–0001, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection is being revised to omit the Inclusion Enrollment Report form, which is being converted to a Common form to include the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. Starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the Grants.gov updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more accurate assessment of the time it takes our applicants to complete the various forms and applications. This collection also continues to includes PHS applications and pre-award

reporting requirements: PHS 398 [paper] Public Health Service Grant Application forms and instructions; PHS 398 [electronic] PHS Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R); PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]; PHS 416–1 Ruth L. Kirschstein National Research Service Award Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]; Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships; PHS 416–5 Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice; and PHS 6031 Payback Agreement. The PHS 398 (paper and electronic are currently approved under 0925–0001. All forms expire 2/28/2023. Post-award reporting requirements are simultaneously consolidated under 0925–0002 and include the Research Performance Progress Report (RPPR). The PHS 398 and SF424 applications are used by applicants to request Federal assistance funds for traditional investigator-initiated research projects and to request access to databases and other PHS resources. The PHS 416–1 is used only for a change of sponsoring institution application. PHS Fellowship Supplemental Form and agency specific instructions is used in combination with the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416–5 is used by individuals to indicate the start of their NRSA awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how

clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements will facilitate NIH's development of data systems to facilitate oversight of clinical trials as well as understand where gaps in the research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with ClinicalTrials.gov.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,023,454.

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
PHS 398 - Paper	4,247	1	35	148,645
PHS 398/424 - Electronic				
PHS Assignment Request Form	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement	74,239	1	1	74,239
PHS 398 Modular Budget	56,693	1	1	56,693
PHS 398 Training Budget	1,122	1	2	2,244
PHS 398 Training Subaward Budget Attachment(s) Form	561	1	90/60	842
PHS 398 Research Plan	70,866	1	10	708,660
PHS 398 Research Training	1,122	1	10	11,220

Program Plan				
Data Tables	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information	54,838	1	13	712,894
Biosketch (424 Electronic)	80,946	1	2	161,892
PHS Fellowship Supplemental Form (includes F reference letters)	6,707	1	12.5	83,838
Biosketch (Fellowship)	6,707	1	2	13,414
416-1	29	1	10	290
PHS 416-5	6,707	1	5/60	559
PHS 6031	6,217	1	5/60	518
VCOC Certification	6	1	5/60	1
SBIR/STTR Funding Agreement Certification	1,500	1	15/60	375
Total	----------	**413,393**	----------	**2,023,454**

Dated: July 30, 2021.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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